

**REMARKS**

This amendment responds to the Office Action mailed May 28, 2003, in which claims 1-22 were pending. In the Office Action the Examiner:

- objected to the drawings under 37 C.F.R. § 1.83(a);
- rejected claims 5, 7, 9-16 and 19 under 35 U.S.C. § 112 ¶ 1;
- rejected claims 1-4, 6, 17, 18 and 20-22 under 35 U.S.C. § 102(a); and
- objected to claim 8.

After entry of this amendment, the pending claims are claims 1-32. New claims 23-32 are presented for the Examiner's consideration. Applicants appreciate the Examiner's indication of allowable subject matter with respect to claim 8.

**I. Objection to the Drawings Under 37 C.F.R. § 1.83**

Replacement drawing sheet 5 of 9 is included in Appendix A. In response to the Examiner's objections to the drawings, applicants have submitted replacement drawing sheet 5 of 9 including the new FIG. 8a. An annotated drawing sheet has also been provided for the Examiner's reference. FIG. 8a shows a detachable blades 440 having a mating portion in the form of a post 620 for reception in bore 60 in jaw 14. The post 620 of blades 440 is shown preferably including a depression 640 for a ball detent attachment within bore or socket 60 and a stop plate 720 for limiting the range of pivotal motion of blade 620 about the longitudinal axis 700. Blades 440 are also shown having distracting surfaces 520 which may preferably further include vertebral engagers 540 and transverse engagement walls 560. No new matter is believed to have been added by this replacement drawing sheet.

Applicants draw the Examiner's attention to the specification and claims of the application as filed for support of the replacement drawing sheet. Specifically, FIG. 8a shows all the features associated with detachable blade as provided in claims 7 and 9-16 as originally filed. In addition, blades 440 of FIG. 8a reflect the described detachable alternative to the *preferred* embodiment of blades 244, shown in Fig. 16 and described at page 12, lines 5-12 of the application as originally filed. The Examiner is respectfully requested to approve the drawing changes. Amendments to the specification are shown above and described below to reflect the changes in replacement drawing sheet 5 of 9.

## **II. Amendment to the Specification**

The specification has been amended accordingly to reference the new figure, Fig. 8a. For reasons stated in remarks related to the replacement drawing sheet and added Fig. 8, no new matter is believed to have been added by these amendments to the specification. These amendments further clarify embodiments of the distractor as previously described in the specification or claims as originally filed. Applicants respectfully request entry of these amendments.

## **III. Claims Rejected Under 35 U.S.C. § 112 ¶ 1**

Claims 5, 7, 9-16, and 19 were rejected under 35 U.S.C. § 112 ¶ 1 for failure to comply with the enablement requirement. As discussed above, these claims were fully enabled by the specification and figures as originally filed. For clarity, however, both the drawings and specification have been amended so as to more fully describe the subject matter of these claims as filed. Applicants respectfully request withdrawal of the rejections based upon 35 U.S.C. § 112.

## **IV. Claims Rejected Under 35 U.S.C. § 102(a)**

### **A. International Patent Application WO 98/34552 to Ray ("Ray")**

Claims 1-4, 6, 17, 18 and 20-22 were rejected under 35 U.S.C. § 102(a) as being anticipated by Ray. Specifically, the Examiner asserted that FIGS. 6, 7 and 8 show a distractor having all the limitations as recited in claims 1-4, 6, 17, 18 and 20-22.

Applicants respectfully traverse this rejection. Claim 1 as filed recites a distractor comprising, *inter alia*, first and second sets of blades wherein, "each comprise at least first and second blades spaced apart to contact anatomical elements to be distracted and permit insertion of an implant." The insertion-distractor tool 21 of Ray does not have first and second sets of blades, each comprising at least first and second blades spaced apart to contact anatomical elements. Instead, the insertion-distractor tool 21 of Ray may include a dual pair of tips or blades 32 which can be used within the lateral stabilizer channels 14 to spread the fusion implant halves 10. (See Ray at 17, lines 6-22, FIGS. 3A, 5, 7 & 8b). Specifically, FIG. 8B of Ray shows the blades 32 in a fixed spatial relationship so as to engage the channels 14 of the *implant* shown in FIG. 3A. Nowhere does Ray teach or suggest the blades 32 or any other blade contact the anatomical elements, (e.g., adjacent vertebrae), rather the insertion-distractor tool 21 is shown and described as being configured for insertion into implant halves 10.

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Therefore, Applicants respectfully assert that the insertion distraction tool 21 of Ray does not have at least first and second blades spaced apart to contact anatomical elements or vertebrae. Applicants therefore respectfully request that the rejection of independent claim 1 based upon anticipation by Ray be withdrawn. Claims 4, 6, 17, 18, 20 and 21 depend from claim 1 and should be allowed for at least the same reasons.

Claim 22 as filed is a method claim reciting a method of distracting adjacent vertebrae comprising, *inter alia*, the steps of providing a distractor comprising first and second jaws, "positioning said first set of spaced apart blades against spaced apart ends of a first vertebral endplate," and "positioning said second set of spaced apart end of a second vertebral endplate adjacent and facing said first vertebral endplate." Ray does not disclose a method of distracting adjacent vertebrae wherein the blades of the distractor are positioned against vertebral endplates. Instead, Ray discloses a method of using an insertion distraction tool 21 having an dual pair of blades 32 to directly engage and spread apart two halves 10 of fusion implant 5. (See Ray at 17, lines 6-8, 16-21; FIGS. 3A, 5, 7 & 8b). Ray describes the method of implanting a fusion implant system and the use of the insertion distraction tool 21. Two bore holes are drilled into adjacent vertebral bodies. (See *id.* at 21, lines 3-9). The two arched halves 10 of the fusion implant device 5 are mounted on the insertion distraction tool 21 and inserted into one of the drilled holes. (*Id.*, lines 10-12). The insertion distraction tool 21 seats the fusion implant device 5 deeply within the hole. (See *id.*, lines 13-16). Distraction of the tool 21 forces the sloped surfaces or sharpened edges 20 of the ribs 11 of the implant halves 10 deeply into the cancellous bone. (*Id.*, lines 16-18; see also *id.* at 17, 16-22). Nowhere does Ray teach or suggest using the insertion or distraction tool 21 in a method of distracting adjacent vertebrae wherein the blades 32 or any other blades disclosed for use with tool 21 are *positioned against vertebral endplates*. Applicants respectfully assert that Ray does not disclose positioning first and second sets of blades against vertebral endplates, and accordingly request that rejection of claim 22 based upon anticipation by Ray be withdrawn.

#### V. New Claims

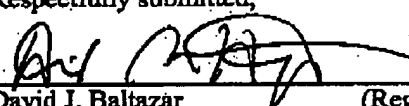
Claims 23-32 have been added to claim additional features. No new matter is believed to have been entered. Applicants respectfully request entry of the new claims.

**VI. Conclusion**

In light of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 202-496-4464, if a telephone call could help resolve any remaining items.

Respectfully submitted,

Date: September 29, 2003

  
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**APPENDIX A**

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Reply to Office Action of May 28, 2003  
Replacement Sheet 5 of 9

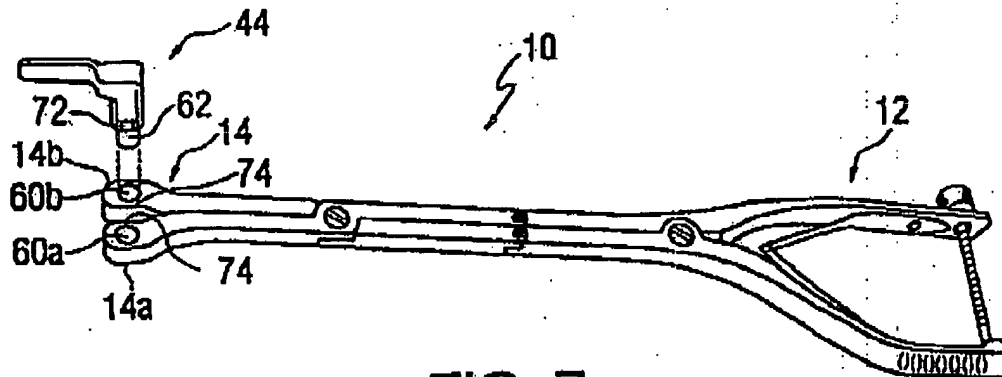


FIG. 7

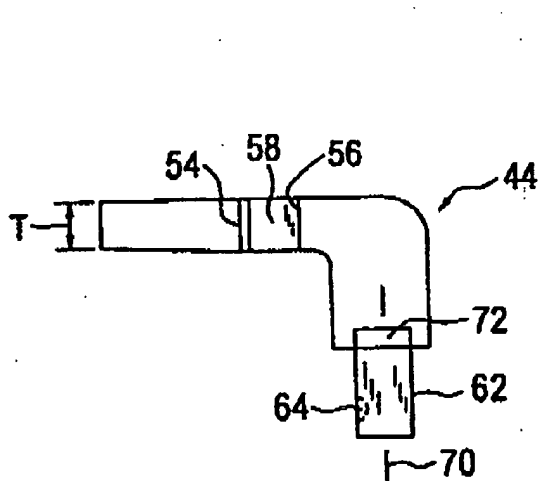


FIG. 8

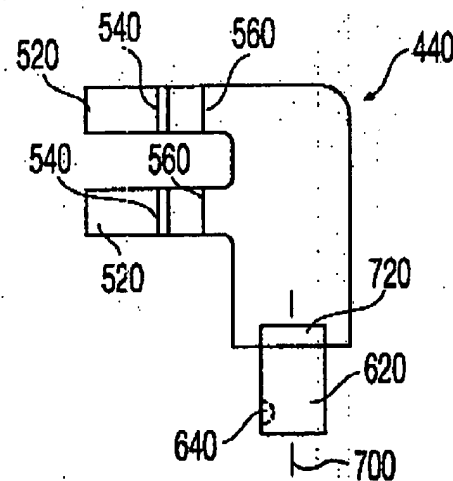


FIG. 8a

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 Reply to Office Action of May 28, 2003  
 Annotated Sheet Showing Changes

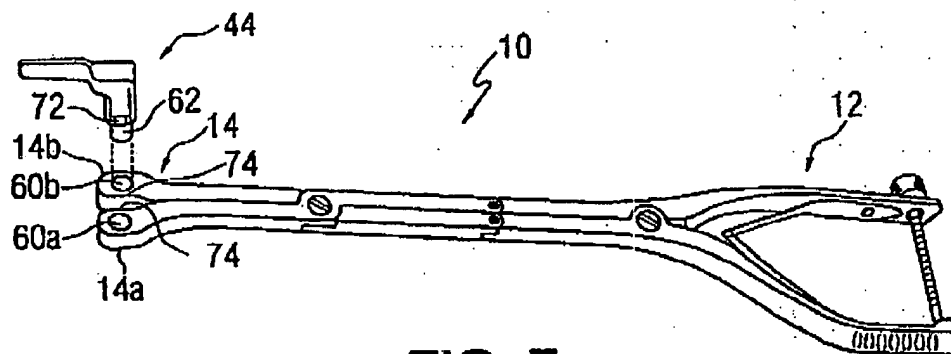


FIG. 7

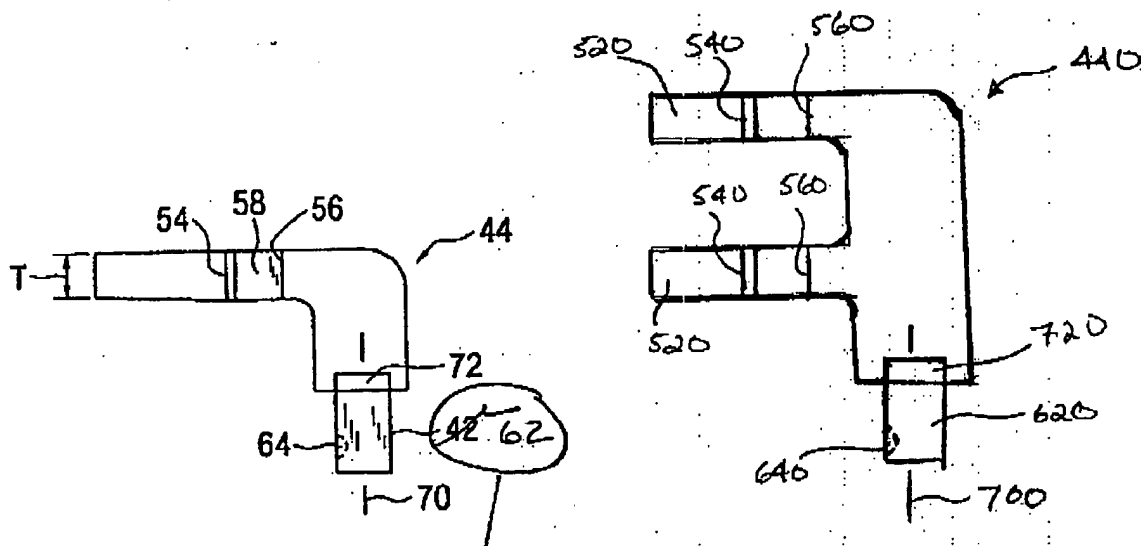


FIG. 8 CORRECTION OF REFERENCE NUMERAL

FIG. 8a (ADDED)